

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Cosuric 100 mg & 300 mg Tablets Allopurinol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Cosuric is and what it is used for
2. What you need to know before you take Cosuric
3. How to take Cosuric
4. Possible side effects
5. How to store Cosuric
6. Contents of the pack and other information

1. What Cosuric is and what it is used for

Cosuric tablets contain a medicine called allopurinol. It works by slowing down the speed of certain chemical reactions in your body to lower the level of uric acid in the blood and urine.

Cosuric is used:

- to reduce or prevent the formation of urate/uric acid deposition in conditions where your body produces too much of a substance called uric acid. These may include gout or some types of kidney stones or certain other types of kidney problems or when you are having treatment for cancer or some other conditions. In gout the uric acid builds up in your joints and tendons as crystals. These crystals cause an inflammatory reaction. The inflammation causes the skin around certain joints to become swollen, tender and sore when only slightly touched. You can also find you get severe pain when the joint is moved.

Use in children is rarely indicated, except in some types of cancer (especially leukaemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.

If you are not sure why you have been prescribed Cosuric, then please ask your doctor.

2. What you need to know before you take Cosuric

Do not take Cosuric if:

- you are allergic (hypersensitive) to allopurinol or any of the other ingredients of Cosuric (listed in section 6).
- you are currently suffering from an acute attack of gout.

If you are not sure, talk to your doctor or pharmacist before taking Cosuric.

Warnings and Precautions

Talk to your doctor or pharmacist before taking your medicine if:

- you are of Han Chinese, African or Indian origin
- you have problems with your liver or kidneys. Your doctor may give you a lower dose or ask you to take it less often than each day. They will also monitor you more closely.

- you have heart problems or high blood pressure and you take diuretics and/or a medicine called ACE-inhibitors.
- you are currently having an attack of gout.
- you have thyroid problems.

Take special care with Cosuric:

- Serious skin rashes (Hypersensitivity syndrome, Stevens- Johnson syndrome, toxic epidermal necrolysis) have been reported in patients taking allopurinol. Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by influenza-like symptoms fever, headache, body ache (flu-like symptoms). The rash may progress to widespread blistering and peeling of the skin. These serious skin reactions can be more common in people of Han Chinese, Thai or Korean origin. Chronic kidney disease may increase the risk in these patients additionally. If you develop a rash or these skin symptoms, **stop taking Cosuric and contact your doctor immediately.**
- If you have cancer or Lesch-Nyhan syndrome the amount of uric acid may increase in your urine. To prevent this, you need to assure to drink sufficiently to dilute your urine.
- In case you have kidney stones, the kidney stones will become smaller and may enter your urinary tract.

Children

Use in children is rarely indicated, except in some types of cancer (especially leukaemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.

Other medicines and Cosuric

Tell your doctor or pharmacist if you are taking any of the following:

- aspirin
- theophylline, used of breathing problems
- medicines used for fits (epilepsy), phenytoin
- vidarabine, used to treat herpes or chickenpox
- antibiotics (ampicillin or amoxicillin)
- didanosine, used to treat HIV infection
- medicines used for cancer
- 6-Mercaptopurine (used to treat blood cancer)
- azathioprine (used to suppress the immune system).The co-administration of 6-mercaptopurine or azathioprine with allopurinol should be avoided. When 6-mercaptopurine or azathioprine is given concurrently with Cosuric, the dose of 6-mercaptopurine or azathioprine should be reduced because their activity will be prolonged. This could increase the risk of serious blood disorders. In this case, your doctor will closely monitor your blood count during treatment.
Seek medical advice immediately if you notice that you have any unexplained bruising, bleeding, fever or sore throat.
- chlorpropamide used in the treatment of diabetes
- medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics) such as captopril, enalapril, lisinopril and ramipril
- medicines used to thin your blood (anticoagulants), such as warfarin
- any other medicine to treat goutsuch as probeneciddiuretics, medicines to increase urine production

If aluminium hydroxide is taken concomitantly, allopurinol may have an attenuated effect. There should be an interval of at least 3 hours between taking both medicines.

With administration of allopurinol and cytostatics (e.g. cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halogenides), blood dyscrasias occur more frequently than when these active substances are administered alone. Blood count monitoring should therefore be performed at regular intervals.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Cosuric can affect the way some Cosuric works. Also some other medicines can affect the Cosuric works.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding. Allopurinol is excreted in the human breast milk. Allopurinol during breast-feeding is not recommended.

Driving and using machines

You may feel drowsy, giddy or have problems with your coordination. If this happens, do not drive or use any tools or machines.

3. How to take Cosuric

Always take Cosuric exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take the tablet after food and swallow it with a glass of water.

You should drink plenty of fluids while you are taking Cosuric.

Your doctor will decide on the most appropriate dose for you depending on the severity of your condition.

Your doctor will usually start with a low dose of allopurinol (e.g. 100 mg/day), to reduce the risk of possible side effects. Your dose will be increased if necessary.

The recommended dose is:

Adults: Initially, a starting dose of 100 mg once a day, this may be increased as follows;

100 - 200 mg daily for mild gout

300 - 600 mg daily for moderately severe gout

700 - 900 mg daily for severe gout

Daily doses more than 300 mg should be taken in divided doses.

Children: Your doctor will decide on the amount of Cosuric to give to your child based on their weight and the condition they are taking the medicine for. The maximum dose is 400 mg daily.

If you are an older person, or have reduced liver or kidney function, your doctor may prescribe a lower dose or ask you to take it at longer intervals.

If you take more Cosuric than you should

If you take more Cosuric than you should, contact a doctor or go to hospital straight away. Take the medicine pack with you. Signs of an overdose may include nausea, vomiting, diarrhoea and dizziness.

If you forget to take Cosuric

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Cosuric

Do not stop taking your Cosuric without talking to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Hypersensitivity

Uncommon (may affect less than 1 in 100 people)

If you have a hypersensitivity (allergic) reaction, stop taking Cosuric and see a doctor straight away. The signs may include:

- flaking skin, boils or sore lips and mouth
- very rarely signs may include sudden wheeziness, fluttering or tightness in the chest and collapse.

Rare (may affect less than 1 in 1000 people)

- fever and chills, headache, aching muscles (flu-like symptoms) and generally feeling unwell
- serious hypersensitivity reactions involving fever, skin rash, joint pain, and abnormalities in blood and liver function tests (these may be signs of a multi-organ sensitivity disorder).
- bleeding in the lips, eyes, mouth, nose or genitals.
- any changes to your skin, for example; ulcers of the mouth, throat, nose, genitals, conjunctivitis (red and swollen eyes), widespread blisters or peeling.

Very rare (may affect less than 1 in 10,000 people)

- serious allergic reaction which causes swelling of the face or throat
- serious potentially life-threatening allergic reaction

Do not take any more tablets unless your doctor tells you to do so.

Other side effects

If you get any of the following side effects, stop taking Cosuric and see your doctor or go to the nearest hospital emergency department straight away:

- serious, potentially life-threatening allergic reactions involving itching, red raised lumps (hives), skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis), appearing initially as reddish target-like spots or circular patches often with central blisters. The rash may progress to widespread blistering or peeling of the skin. Additional signs include swelling of the face, tongue or throat which may cause difficulty breathing and wheezing, ulcers in the mouth, throat, nose or genitals, sore mouth and lips, red swollen eyes (conjunctivitis), enlarged lymph glands, fever, joint pain, flu-like symptoms and abnormal liver function tests

If you develop these conditions with Cosuric, you **must not** restart taking this medicine at any time.

If you get any of the following serious side effects, see a doctor as soon as possible:

- changes to your blood, such as altered numbers of white blood cells, red blood cells or blood platelets. This may cause symptoms including unexplained bleeding, bruising, increased risk of infections, sore throat, fever, weakness, breathlessness, pale skin or general illness. A blood test should be taken. These effects are more likely to occur in people with liver or kidney problems.

Common (may affect up to 1 in 10 people)

- skin rash
- increased level of thyroid stimulating hormone in the blood

Uncommon (may affect up to 1 in 100 people)

- feeling sick (nausea) or being sick (vomiting)
- abnormal liver function tests
- diarrhoea

Rare (may affect up to 1 in 1000 people)

- inflammation of the liver (hepatitis), the symptoms of which include yellowing of the skin or whites of the eyes (jaundice), darker urine and paler stools

Very rare (may affect up to 1 in 10,000 people)

- occasionally Cosuric tablets may affect your blood, which can manifest as bruising more easily than usual, or you may develop a sore throat or other signs of an infection. These effects usually occur in people with liver or kidney problems. Tell your doctor as soon as possible.
- Cosuric may affect the lymph nodes
- high temperature
- blood in your urine (haematuria) and excess fat in stools
- high levels of cholesterol in your blood (hyperlipidaemia)
- a general feeling of being unwell or feeling weak
- weakness, numbness, unsteadiness on your feet, feeling unable to move muscles (paralysis) or loss of consciousness
- headache, dizziness, drowsiness or disturbance of your vision

- chest pain (angina), high blood pressure or a slow pulse
- male infertility or erectile dysfunction
- enlargement of breasts, in men as well as women
- a change in your normal bowel habit
- a change in taste
- cataracts
- hair loss or discolouration
- depression
- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)
- build up of fluid in tissues causing swelling (oedema) particularly of your ankles
- abnormal glucose metabolism (diabetes). Your doctor may wish to measure the level of sugar in your blood to check if this is happening.

Not known (can not be estimated from available data):

Lichenoid skin rash (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes).

Aseptic meningitis (inflammation of the membranes that surround the brain and spinal cord): symptoms include neck stiffness, headache, nausea, fever or consciousness clouding. Seek medical attention immediately if these occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cosuric

- **Keep this medicine out of the sight and reach of children.**
- Keep your medicine in a dry place, below 25°C. Keep the tablets in the container in which they were given to you.
- Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste.
- Return any unused or unwanted tablets to your pharmacist for disposal. Only keep them if your doctor tells you to. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cosuric Tablets contain

The active substance is allopurinol. Each Cosuric 100 mg Tablet contains 100 mg allopurinol and each Cosuric 300 mg Tablet contains 300 mg allopurinol.

The other ingredients are crospovidone, polyethylene glycol 6000, dextrose monohydrate and stearic acid.

What Cosuric Tablets look like and contents of the pack

Cosuric 100 mg Tablets are white round tablets marked 'COSURIC 100'.

Cosuric 300 mg Tablets are white round tablets marked 'COSURIC 300'.

Both strengths of Cosuric Tablets are available in containers of 16, 21, 28, 30, 50, 56, 60, 84, 90, 112, 120, 140, 150, 168, 180, 250, 1000, 5000, 50000 tablets, and in blister packs of 16, 21, 50, 56, 60, 84, 90, 100, 112, 120, 140, 150, 168, 180 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chelonia Healthcare Limited
Boumpoulinas 11, 3rd Floor, Nicosia, P.C. 1060, Cyprus

Manufacturer

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For any information about this medicine, please contact the Marketing Authorisation Holder.

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